

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0861701	(X3) Date Survey Completed 05/24/2023
Name of Provider or Supplier North Dallas Urology Assoc	Street Address, City, State 5300 W Plano Pkwy Suite 200, Plano, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5032	<p>CYTOLOGY CFR(s): 493.1221</p> <p>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for an annual statistical evaluation for three of three nongynecologic cytology statistics (refer to D5629); failed to establish written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish written policies and procedures to ensure that the workload limit would be prorated when examining slides in less than eight hours (refer to D5641); and failed to establish written policies and procedures to ensure unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory (refer to D5655).</p>
D5629	<p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> <p>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were</p>

available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and an interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures for an annual statistical evaluation for three of three required nongynecologic cytology statistics. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation for three of three required nongynecologic cytology statistics. Statistics include: -The number of cytology cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. During an interview on May 24, 2023 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings.

D5633

CYTOLOGY

CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:

Based on lack of workload limit policies and procedures and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure the Technical Supervisor established maximum workload limits for the Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the Technical Supervisor established maximum workload limits for the Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimens. 2. During an interview on May 24, 2023 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings.

D5637

CYTOLOGY

CFR(s): 493.1274(d)(1)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:

Based on lack of workload limit policies and procedures and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Laboratory Director/Technical Supervisor. Findings include: 1. The Survey Team requested and the laboratory failed to provide

written policies and procedures to describe how the Technical Supervisor would reassess and adjust a maximum workload limit for the Laboratory Director/Technical Supervisor at least every six months. 2. During an interview on May 24, 2023 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings.

D5641

CYTOLOGY
CFR(s): 493.1274(d)(2)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, review of workload records and interview the laboratory failed to establish written policies and procedures to ensure that the workload limits for the Laboratory Director/Technical Supervisor would be prorated when examining slides in less than eight hours. The laboratory failed to prorate work load limits for each day the Laboratory Director/Technical Supervisor evaluated cytology slides in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Laboratory Director/Technical Supervisor when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for the Laboratory Director/Technical Supervisor when examining slides in less than eight hours. 3. During an interview on May 24, 2023 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings.

D5647

CYTOLOGY
CFR(s): 493.1274(d)(4)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.

This STANDARD is not met as evidenced by:
Based on lack of workload limit policies and procedures, lack of workload limit records and interview the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for the Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide records of an established maximum workload limit for the Laboratory Director/Technical Supervisor/ in 2021, 2022 and to the date of the survey in 2023. 3. During an interview on May 24, 2023 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings.

<p>D5655</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(4)</p> <p>(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish written policies and procedures to ensure unsatisfactory nonngynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory for evaluation. 2. During an interview on May 24, 2023 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings.</p>
<p>D6130</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3)</p> <p>(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k) (2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of workload limit assessment records and interview with the Laboratory Director/Technical Supervisor the Technical Supervisor failed to establish a maximum workload limit and reassess workload limits at least every six months for the Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Technical Supervisor failed to establish and reassess a maximum workload limit for the Laboratory Director/Technical Supervisor who performed primary cytology slide examinations in 2021, 2022 and to the date of the survey in 2023. (refer to D5633, D5637 and D5647). 2. During an interview on May 24, 2023 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings.</p>
<p>D9999</p>	<p>By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.</p>